REMARKS

In the aforesaid Office Action, claims 26 was rejected under 35 USC § 112, second paragraph, claims 26, 28-29, 34 and 35 were rejected under 35 USC § 102(b) as being anticipated by Wang et al. (US 5,556,383), and claims 30-33, 36 and 37 were rejected under 35 USC § 103(a) as being unpatentable over Wang et al. alone. Claims 26 and 28-37 are pending.

The Examiner rejected claim 26 under 35 USC § 112, second paragraph, stating that it is not clear if the inflated outer diameter radial shrinkage is measured based on two different inflated pressures (one in the balloon mold and another as part of a catheter). However, the radial shrinkage of the balloon should be understood to refer to the amount by which the blow molded outer diameter of the balloon shrinks. Specifically, blow-molded balloons have an inflated shape corresponding to the inner shape of the balloon mold used to blow-mold the balloon (in the deflated state, the excess balloon material is typically formed into wings wrapped around the catheter to form a low profile configuration, which unwrap as the balloon inflates). As a result, balloons are understood to have an inflated outer diameter (commonly referred to as the "nominal" outer diameter) resulting from the volume of the blow-molded balloon being filled with inflation fluid at an inflation pressure which is therefore commonly referred to as the "nominal" pressure, without stretching/distending the blow-molded wall beyond the nominal outer diameter which results from just filling the blow-molded volume of the balloon. In the absence of "radial shrinkage" as defined in Applicant's claims, filling the

blow-molded volume of the balloon with inflation fluid would result in an inflated outer diameter equal to the inner diameter of the balloon mold. Consequently, the "radial shrinkage" of the balloon set forth in Applicant's claim 26 should be understood to refer to the amount by which the inflated outer diameter of the balloon at the inflation pressure required to just fill the blow-molded volume of the balloon as part of a catheter is less than the inner diameter of the balloon mold used to form the balloon. Applicants have amended claim 26 accordingly.

The Examiner states that Wang et al. discloses balloons having radial distention % or shrinkage % from the inflated outer diameters of the balloons to the inner diameters of the molds at ambient temperature at 4.2% (example 1) or 3.2% (example 2) when inflated from 88 psi to 132 psi, and that when one gradually increases the internal pressure inside the balloon, Wang balloon is gradually expanded and when one gradually decreases the internal pressure of the Wang balloon, the balloon will shrink and achieve shrinkage percentages as recited in the claims.

However, the Examiner appears to have misinterpreted the radial shrinkage percentages set forth in Applicant's claims. Specifically, as discussed above, the radial shrinkage refers to the difference between the diameter to which the blow-molded balloon inflates by merely filling the blow-molded volume of the balloon with inflation fluid (e.g., without stretching/distending the balloon wall) and the inner diameter of the mold used to blow-mold the balloon (i.e., the outer diameter of the balloon in the mold, inflated into contact with the inner surface of the mold). In contrast, the distension of the balloons of Wang (4.2% in example 1; 3.2% in example 2) is a measure of how much the

balloon wall is stretching/distending beyond the nominal outer diameter (2.25 mm or 3.00 mm) as the inflation pressure is increased from the nominal pressure (88 psi) to a pressure above nominal pressure (see Wang, col. 1, lines 40-60 for a discussion of the distension of the balloon above the nominal diameter). Therefore, Wang is discussing the distension of the balloon beyond the nominal diameter of the balloon, whereas Applicant's claims are directed to a balloon which has limited radial shrinkage of the nominal diameter of the balloon as discussed above.

Claim 26 explicitly defines the radial shrinkage as the difference between the inner diameter of the balloon mold used to blow-mold the balloon and the inflated outer diameter of the balloon at an inflation pressure required to fill the blow-molded inflated volume at an ambient temperature as part of a catheter system after exposure to a shrinking treatment which causes the radial shrinkage. Therefore, Applicant's claim 26 explicitly defines the radial shrinkage such that it is clearly not merely the deflation of the balloon. Thus, although the balloon of Wang will gradually expand as one gradually increases the internal pressure inside the balloon and shrink when one gradually decreases the internal pressure of the Wang balloon, doing so does not disclose or suggest a balloon which will achieve the shrinkage percentages required by Applicant's claims.

Applicants wish to bring to the attention of the Patent Office the reference listed on the attached PTO-1449, and request that it be considered by the Examiner. This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(c)(2), and therefore the fee set forth in rule 1.17(p) is due.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

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